General

Guideline Title

American Society of Clinical Oncology clinical practice guideline update on the use of chemotherapy sensitivity and resistance assays.

Bibliographic Source(s)

Burstein HJ, Mangu PB, Somerfield MR, Schrag D, Samson D, Holt L, Zelman D, Ajani JA, American Society of Clinical Oncology. American Society of Clinical Oncology clinical practice guideline update on the use of chemotherapy sensitivity and resistance assays. J Clin Oncol. 2011 Aug 20;29(24):3328-30. [7 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Schrag D, Garewal HS, Burstein HJ, Samson DJ, Von Hoff DD, Somerfield MR. American Society of Clinical Oncology Technology Assessment: chemotherapy sensitivity and resistance assays. J Clin Oncol. 2004 Sep 1;22(17):3631-8.

Recommendations

Major Recommendations

Note: The Update Committee determined that no changes to the 2004 recommendations are warranted. These recommendations are listed below.

Use of Chemotherapy Sensitivity and Resistance Assays (CSRAs)

The use of CSRAs to select chemotherapeutic agents for individual patients is not recommended outside of the clinical trial setting.

Chemotherapy Treatment Decisions

Oncologists should make chemotherapy treatment recommendations on the basis of published reports of clinical trials and a patient's health status and treatment preferences.

Future Research: Evaluating CSRAs in Clinical Trials

Because the in vitro analytic strategy has potential importance, participation in clinical trials evaluating these technologies remains a priority.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Non-hematologic cancer

Guideline Category

Technology Assessment

Clinical Specialty

Oncology

Pathology

Intended Users

Physicians

Guideline Objective(s)

To update the American Society of Clinical Oncology (ASCO) Technology Assessment guidelines on chemotherapy sensitivity and resistance assays (CSRAs) published in 2004

Target Population

Patients with non-hematologic cancer who require chemotherapy

Interventions and Practices Considered

Use of chemotherapy sensitivity and resistance assays (CSRAs) in the selection of chemotherapeutic agents in order to inform individual patient treatment regimens (only in clinical settings)

Major Outcomes Considered

- Clinical utility of chemotherapy sensitivity and resistance assays (CSRAs)
- Survival, including overall survival (OS) and/or response to therapy, disease-free survival, progression-free survival
- Tumor response

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An Update Working Group reviewed data published between December 1, 2003, and May 31, 2010. MEDLINE and the Cochrane Library were searched. The literature search yielded 11,313 new articles. The limits for "human and English" were used, and then standard American Society of Clinical Oncology (ASCO) search strings for randomized controlled trials, meta-analyses, guidelines, and reviews were added, yielding 1,298 articles for abstract review. Of these, only 21 articles met predefined inclusion criteria and underwent full text review, and five reports of randomized controlled trials were included for data extraction.

The relevant literature was identified using the search strategy outlined in the Data Supplement (see the "Availability of Companion Documents" field). As with the previous ASCO guideline on chemotherapy sensitivity and resistance assays (CSRAs), the following criteria for selection were applied to each publication: inclusion and exclusion criteria included outcome comparisons (prospective or retrospective) for patients whose chemotherapy was chosen empirically (based on clinical trial literature) as opposed to selection based on results of CSRAs; CSRA performance on viable patient tumor tissue as opposed to other forms of diagnostic testing performed on nonviable tumor tissue; a study sample size of ≥20 patients per arm; and primary end points of cancer events or survival including overall survival (OS) and/or response to therapy, disease-free survival, progression-free survival, local tumor control, and/or treatment toxicity.

Number of Source Documents

Twenty-one articles met predefined inclusion criteria and underwent full text review for the update, and five reports were included for data extraction.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

After a careful review of the literature, data were extracted for the following chemotherapy sensitivity and resistance assays (CSRAs): adenosine triphosphate bioluminescence (ATP; n = 2 publications), extreme drug resistance assay (EDRA; n = 1 publication), methyl-thiazolyl-diphenyl-tetrazolium bromide (MTT; n = 1 publication), and ChemoFX (Precision Therapeutics, Pittsburgh, PA; n = 1 publication). A synopsis of each of these publications can be found in the original guideline document.

An evidence table with data from the new studies is provided as a Data Supplement (see the "Availability of Companion Documents" field). An overview of the CSRAs, as it appeared in the original guideline, is also provided as a Data Supplement.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American Society of Clinical Oncology (ASCO) Technology Assessment: Chemotherapy Sensitivity and Resistance Assays (CSRA) was first published in 2004. ASCO guidelines (some previously titled Technology Assessments) are updated at intervals, and this update reflects new evidence but no change in the recommendations from the original guideline. It summarizes the updated literature and includes a brief discussion.

For the 2011 Update, an ASCO Update Committee/Working Group was composed of members of the full 2004 original CSRA Guideline Panel.

The Update Committee addressed the same clinical questions as the original guideline:

1. Is there a clear definition of what constitutes a successful assay?
2. Do assay results depend on the particular lesion biopsied?
3. Does the assay-guided therapy affect the choice of chemotherapy agent?
4. Most critically, the group again asked: "Does the assay yield clinically useful results?"

The Working Group of the Update Committee drafted the manuscript and circulated it via e-mail to the full Update Committee for review and approval.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The American Society of Clinical Oncology's Clinical Practice Guideline Committee leadership reviewed and approved the final document on April 27, 2011.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting each recommendation is not specifically stated. The recommendations are based on a critical review of the current scientific and clinical information.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of chemotherapy sensitivity and resistance assays (CSRAs) as a tool in recommending chemotherapy treatment regimens

Qualifying Statements

Qualifying Statements

The practice guideline is not intended to substitute for the independent professional judgment of the treating physician. Practice guidelines do not account for individual variation among patients and may not reflect the most recent evidence. This guideline does not recommend any particular product or course of medical treatment. Use of the practice guideline is voluntary.

Implementation of the Guideline

Description of Implementation Strategy

For information on the American Society for Clinical Oncology (ASCO) implementation strategy, please see the ASCO Web site .

Implementation Tools

Patient Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2004 Aug 2 (revised 2011 Aug 20)

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology (ASCO)

Guideline Committee

2011 Update Committee/Working Group for the American Society of Clinical Oncology Update on the Use of Chemotherapy Sensitivity and Resistance Assays

Composition of Group That Authored the Guideline

Update Committee Members: Harold J. Burstein, MD, PhD (*Co-Chair**), Dana-Farber Cancer Institute, Boston, MA; Jaffer Ajani, MD (*Co-Chair**), The University of Texas MD Anderson Cancer Center, Houston, TX; Lawrence Holt, MD, Coastal Cancer Center, Myrtle Beach, SC; David Samson*, Blue Cross Blue Shield Association; Deborah Schrag, MD, Dana-Farber Cancer Institute, Boston, MA; Debra Zelman, Patient Representative, Debbie's Dream, Davie, FL

*Working Group Member

Financial Disclosures/Conflicts of Interest

The Update Committee was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflict of Interest Management Procedures for Clinical Practice Guidelines (summarized at http://www.asco.org/guidelinescoi). Members of the Update Committee completed ASCO's disclosure form, which requires disclosure of financial and other interests that are relevant to the subject matter of the guideline, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment relationships, consulting arrangements, stock ownership, honoraria, research funding, and expert testimony. In accordance with the Conflict of Interest Management Procedures, the majority of the members of the Update Committee did not disclose any such relationships.

The author(s) indicated no potential conflicts of interest.

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Guideline Availability

Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site .

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; E-mail: guidelines@asco.org.

Availability of Companion Documents

The following are available:

- American Society of Clinical Oncology clinical practice guideline update on the use of chemotherapy sensitivity and resistance assays. Data supplement. Alexandria (VA): American Society of Clinical Oncology; 2011. 12 p. Electronic copies: Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site.
- American Society of Clinical Oncology clinical practice guideline update on the use of chemotherapy sensitivity and resistance assays. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2011. 14 p. Electronic copies: Available in PDF and PowerPoint from the ASCO Web site.

Patient Resources

The following is available:

- Tests to help choose chemotherapy. Patient guide. Electronic copies: Available from the Cancer.Net Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI on September 24, 2004. The information was verified by the guideline developer on September 24, 2004. This NGC summary was updated by ECRI Institute on December 20, 2013.

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